AMENDED IN ASSEMBLY JUNE 13, 2012

AMENDED IN ASSEMBLY JUNE 6, 2012

SENATE BILL No. 1481

Introduced by Senator Negrete McLeod

February 24, 2012

An act to amend Sections 1241 and 4052.4 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

SB 1481, as amended, Negrete McLeod. Clinical laboratories: community pharmacies.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health, subject to certain exceptions. Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to perform skin puncture in the course of performing clinical laboratory tests classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA).

This bill would exempt a community pharmacy that solely provides certain tests classified as waived under CLIA from the clinical laboratory regulations *and approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit*, provided that the tests are performed by a pharmacist, as specified, the pharmacy obtains a CLIA certificate of waiver and complies with all other requirements under CLIA, and the pharmacy notifies the public health officer of the county in which the pharmacy is located that the pharmacy is performing those tests.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1241 of the Business and Professions Code is amended to read:

1241. (a) This chapter applies to all clinical laboratories in California or receiving biological specimens originating in California for the purpose of performing a clinical laboratory test or examination, and to all persons performing clinical laboratory tests or examinations or engaging in clinical laboratory practice in California or on biological specimens originating in California, except as provided in subdivision (b).

(b) This chapter shall not apply to any of the following clinical laboratories, or to persons performing clinical laboratory tests or examinations in any of the following clinical laboratories:

(1) Those owned and operated by the United States of America, or any department, agency, or official thereof acting in his or her official capacity to the extent that the Secretary of the federal Department of Health and Human Services has modified the application of CLIA requirements to those laboratories.

(2) Public health laboratories, as defined in Section 1206.

(3) Those that perform clinical laboratory tests or examinations for forensic purposes only.

(4) Those that perform clinical laboratory tests or examinations for research and teaching purposes only and do not report or use patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or for the assessment of the health of, an individual.

(5) Those that perform clinical laboratory tests or examinations certified by the National Institutes on Drug Abuse only for those certified tests or examinations. However, all other clinical laboratory tests or examinations conducted by the laboratory are subject to this chapter.

(6) Those that register with the State Department of Public Health pursuant to subdivision (c) to perform blood glucose testing for the purposes of monitoring a minor child diagnosed with diabetes if the person performing the test has been entrusted with

the care and control of the child by the child's parent or legal guardian and provided that all of the following occur:

(A) The blood glucose monitoring test is performed with a blood glucose monitoring instrument that has been approved by the federal Food and Drug Administration for sale over the counter to the public without a prescription.

(B) The person has been provided written instructions by the child's health care provider or an agent of the child's health care provider in accordance with the manufacturer's instructions on the proper use of the monitoring instrument and the handling of any lancets, test strips, cotton balls, or other items used during the process of conducting a blood glucose test.

(C) The person, receiving written authorization from the minor's parent or legal guardian, complies with written instructions from the child's health care provider, or an agent of the child's health care provider, regarding the performance of the test and the operation of the blood glucose monitoring instrument, including how to determine if the results are within the normal or therapeutic range for the child, and any restriction on activities or diet that may be necessary.

(D) The person complies with specific written instructions from the child's health care provider or an agent of the child's health care provider regarding the identification of symptoms of hypoglycemia or hyperglycemia, and actions to be taken when results are not within the normal or therapeutic range for the child. The instructions shall also contain the telephone number of the child's health care provider and the telephone number of the child's parent or legal guardian.

(E) The person records the results of the blood glucose tests and provides them to the child's parent or legal guardian on a daily basis.

(F) The person complies with universal precautions when performing the testing and posts a list of the universal precautions in a prominent place within the proximity where the test is conducted.

(7) Those individuals who perform clinical laboratory tests or examinations, approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, on their own bodies or on their minor children or legal wards.

(8) Those certified emergency medical technicians and licensed paramedics providing basic life support services or advanced life support services as defined in Section 1797.52 of the Health and Safety Code who perform only blood glucose tests that are classified as waived clinical laboratory tests under CLIA, if the provider of those services obtains a valid certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations.

(9) A community pharmacy that is providing only blood glucose, hemoglobin A1c, or cholesterol tests classified as waived under CLIA *and approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit*, provided that all of the following requirements are satisfied:

(A) The pharmacy obtains a valid CLIA certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations.

(B) The tests are performed by a pharmacist, as defined in Section 4036, in the course of performing routine patient assessment procedures in compliance with Section 4052.4.

(C) The pharmacy notifies the public health officer of the county in which the pharmacy is located that the pharmacy is performing one or more of the tests identified in this paragraph.

(c) Any place where blood glucose testing is performed pursuant to paragraph (6) of subdivision (b) shall register by notifying the State Department of Public Health in writing no later than 30 days after testing has commenced. Registrants pursuant to this subdivision shall not be required to pay any registration or renewal fees nor shall they be subject to routine inspection by the State Department of Public Health.

SEC. 2. Section 4052.4 of the Business and Professions Code is amended to read:

4052.4. Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or paragraph (9) of subdivision (b) of Section 1241. For purposes of this section, “routine patient assessment procedures” means: (a) procedures that a patient could, with or without a prescription,

perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or paragraph (9) of subdivision (b) of Section 1241. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

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